

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of : Group Art Unit: Not Yet Assigned
ROSS *et al.* :
Appln. No.: NOT YET ASSIGNED : Examiner: Not Yet Assigned
Filed: HEREWITH : Attorney Docket
For: BREAST CANCER RESISTANCE : No. 10460-7U1
PROTEIN (BCRP) AND THE DNA : (053836-5001-01)
WHICH ENCODE IT :

PRELIMINARY AMENDMENT

Preliminary to the examination of the above-captioned application, please amend the application as follows:

In the Specification:

Please add the following statement to the specification on page 1, line 1:

This application is a divisional of U.S. Patent Application No. 09/245,808, filed February 5, 1999 which claims priority under 35 U.S.C. § 119(e) to provisional Application No.60/073,763 filed February 5, 1998.

In the Claims:

Please cancel claims 1-4, 8-11, 16-17, and 19-20, without prejudice to the inclusion of the subject matter contained therein in any later filed continuation or divisional application.

Please amend claims 5, 12-15, and 18 as indicated in the "Marked Up Copy of the Claims" sheet included herewith. Deletions are indicated with brackets, and additions are underlined. A "Clean Copy of the Claims", which lists all currently pending claims in their amended form, is also enclosed herewith.

Please add claims 21-28 as indicated on the "Clean Copy of the Claims" sheet included herewith.

REMARKS

Claims 5-7, 12-15, 18, and 21-28 are pending in the present application.

Applicants have amended the specification herein to claim benefit to an earlier filing date as well as to cross-referenced related applications.

Claims 1-4, 8-11, 16-17, and 19-20 have been canceled by way of the present Preliminary Amendment. Claims 5, 12-15, and 18 have been amended herein. Claims 5 and 12 have been amended to eliminate reference to canceled claims. In addition, claims 12-15 and 18 have been amended to add clarity. The material content of the amended claims is unchanged. A "Marked Up Copy of the Claims" and a "Clean Copy of the Claims" is enclosed herewith.

Applicants request that claims 21-28 be added to the application, as indicated in the "Clean Copy of the Claims" enclosed herewith.

Claims 21-25 are drawn to diagnostic and therapeutic methods using an antibody to BCRP. These claims are supported by the specification as filed and thus, do not add new matter. Specifically, support for these claims is found on page 10, lines 9-20.

Claims 26-28 are drawn to a method of determining the cause of chemotherapy drug resistance in a cell using an inhibitor of BCRP. These claims are supported by the specification at page 16, line 18 and page 35, line 17.

No new matter has been added by way of this Preliminary Amendment.

Favorable examination of the claims on the merits is respectfully requested.

Respectfully submitted,

ROSS, *et al.*

SEPTEMBER 24, 2001
(Date)

By: Kathryn Doyle
KATHRYN DOYLE, Ph.D, J.D.
Registration No. 36,317
MORGAN, LEWIS & BOCKIUS, LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000
Direct Dial: (215) 963-4723
Facsimile: (215) 963-5299
E-Mail: kdoyle@morganlewis.com
Attorney for Applicants

KD/JAI

Enclosures: Marked Up Copy of the Claims
Clean Copy of the Claims

MARKED UP COPY OF THE CLAIMS

5. (Amended) An antibody which binds to [the protein of claim 1] a Breast Cancer Resistance Protein which protein induces resistance to cancer chemotherapeutic drugs, or fragments or derivatives thereof.

12. (Amended) A method of determining [the cause of a patient's resistance] whether a patient is resistant to cancer chemotherapy drugs, [by assaying for] the method comprising assessing the expression of [the protein of claim 1] a Breast Cancer Resistance Protein which protein induces resistance to cancer chemotherapeutic drugs, or fragments or derivatives thereof, in a cell of said patient, whereby overexpression of [the] said protein [indicates that it is the cause] establishes that said patient is resistant to said cancer chemotherapy.

13. (Amended) A method of inhibiting the activity of [the] Breast Cancer Resistance Protein in a patient's cell, said method comprising [by] administering the antibody of claim 5 to said patient, thereby inhibiting the activity of said Breast Cancer Resistance Protein.

14. (Amended) A method of inhibiting the activity of [the] Breast Cancer Resistance Protein in a patient's cell, said method comprising [by] administering the antibody of claim 6 to said patient, thereby inhibiting the activity of said Breast Cancer Resistance Protein.

15. (Amended) A method of inhibiting the activity of [the] Breast Cancer Resistance Protein in a patient's cell, said method comprising [by] administering the antibody of claim 7 to said patient, thereby inhibiting the activity of said Breast Cancer Resistance Protein.

18. (Amended) A method of enhancing a cancer patient's chemotherapy treatment, [by administering] said method comprising inhibiting the activity of Breast Cancer Resistant Protein in a patient's cell by administering the antibody of claim 5, thereby inhibiting said Breast Cancer Resistance Protein.

CLEAN COPY OF THE CLAIMS

5. (Amended) An antibody which binds to a Breast Cancer Resistance Protein which protein induces resistance to cancer chemotherapeutic drugs, or fragments or derivatives thereof.

6. The antibody of claim 5 which is monoclonal.

7. The antibody of claim 5 which is polyclonal.

12. (Amended) A method of determining whether a patient is resistant to cancer chemotherapy drugs, the method comprising assessing the expression of a Breast Cancer Resistance Protein which protein induces resistance to cancer chemotherapeutic drugs, or fragments or derivatives thereof, in a cell of said patient, whereby overexpression of said protein establishes that said patient is resistant to said cancer chemotherapy.

13. (Amended) A method of inhibiting the activity of Breast Cancer Resistance Protein in a patient's cell, said method comprising administering the antibody of claim 5 to said patient, thereby inhibiting the activity of said Breast Cancer Resistance Protein.

14. (Amended) A method of inhibiting the activity of Breast Cancer Resistance Protein in a patient's cell, said method comprising administering the antibody of claim 6 to said patient, thereby inhibiting the activity of said Breast Cancer Resistance Protein.

15. (Amended) A method of inhibiting the activity of Breast Cancer Resistance Protein in a patient's cell, said method comprising administering the antibody of claim 7 to said patient, thereby inhibiting the activity of said Breast Cancer Resistance Protein.

18. (Amended) A method of enhancing a cancer patient's chemotherapy treatment, said method comprising inhibiting the activity of Breast Cancer Resistant Protein in a patient's cell by administering the antibody of claim 5, thereby inhibiting said Breast Cancer Resistance Protein.

21. (New) A method of enhancing a cancer patient's chemotherapy treatment, said method comprising inhibiting the activity of Breast Cancer Resistant Protein in a patient's cell by administering the antibody of claim 6, thereby inhibiting said Breast Cancer Resistance Protein.

22. (New) A method of enhancing a cancer patient's chemotherapy treatment, said method comprising inhibiting the activity of Breast Cancer Resistant Protein in a patient's

cell by administering the antibody of claim 7, thereby inhibiting said Breast Cancer Resistance Protein.

23. (New) The method of claim 12, wherein overexpression of said protein is detected using the antibody of claim 5.

24. (New) The method of claim 12, wherein overexpression of said protein is detected using the antibody of claim 6.

25. (New) The method of claim 12, wherein overexpression of said protein is detected using the antibody of claim 7.

26. (New) A method of determining the cause of a cell's resistance to cancer chemotherapy drugs, said method comprising:

a) exposing drug-resistant cells to the fluorescent aza-anthrapyrazole BBR3390 in the presence or absence of an inhibitor of Breast Cancer Resistance Protein;

b) measuring the intracellular level of BBR390 in said cells;

c) comparing the intracellular level of BBR390 in said cells in the presence of said inhibitor to the level of BBR390 in said cells in the absence of said inhibitor,

wherein a reduction in the accumulation of BBR390 in said cells treated with BBR3390 in the presence of said inhibitor is an indication that drug resistance in said cells is caused by overexpression of Breast Cancer Resistance Protein.

27. (New) The method of claim 26, wherein said inhibitor is fumitremorgin C (FTC).

28. (New) The method of claim 26, wherein said drug resistant cells are obtained from a cancer patient and said method is used to determine the cause of chemotherapy drug resistance in said patient.